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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/402,614 | 03/01/2000 | GAIL PETUNA RISBRIDGER | 229752000800 | 6186 |
| 7590 MORRISON & FOERSTER LLP 1650 TYSONS BLVD SUITE 300 MCLEAN, VA 22102 | | | EXAMINER | |
| | | | YAO, LEI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |
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| | | | 12/22/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/402,614 | Applicant(s) RISBRIDGER ET AL. |
| | Examiner LEI YAO | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 25 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26,40-58,60-63,69,72-93,95,96,98 and 99 is/are pending in the application.
- 4a) Of the above claim(s) 1-26,40-57,61 and 92 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 58,60,62,63,69,72-91,93,95,96,98 and 99 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

Response to Amendment and Arguments

The remarks filed on 9/25/2008 in response to the previous Non-Final Office Action (3/25/2008) are acknowledged and has been entered. There is no amendment to the claims filed currently.

Claims 1-26, 40-58, 60-63, 69, 72-93, 95, 96, 98 and 99 are pending.

Claims 1-26, 40-57, 61 and 92 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claims.

Claims 58, 60, 62, 63, 69, 72-91, 93, 95, 96, 98 and 99, drawn to a method of screening a down regulation of inhibin protein for indicating a developed prostate cancer, are under consideration.

Drawings

It is acknowledged that replaced drawings are filed on 9/25/2008.

Rejection Maintained

Double Patenting

Claims 58, 60, 62, 63, 69, 72-91, 93, 95, 96, 98 and 99 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. **10551352 and 11/578711**.

Applicant acknowledges that these are provisional rejections and does not intend to take further action at this time because the instant application is earlier-filed

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application. Thus, the rejection is maintained until the allowable subject matter is identified.

Rejection Maintained and Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement Rejection

Claims 58, 60, 62, 63, 69, 72-91, 93, 95, 96, 98 and 99 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Previous response to applicant's argument dated 11/21/2007 is also maintained for the reason of record as set forth in the Office action dated 3/25/2008.

First, Applicant refers interview (4/23/2007) and argues:

Applicants do not assert to have discovered a method to affirm the absence of prostate cancer, and the claims do not recite a method of affirming the absence of prostate cancer with 100% certainty. The claims recite that the down-regulation of inhibin is indicative of having prostate cancer, and the down-regulation of inhibin has been a persistent indicator of the presence of prostate cancer as claimed.

The Examiner has not cited a reference that illustrates a conflicting finding.

Applicant further argues:

the claimed screening methods are not rendered "not enabled" simply because the screening method cannot affirm with 100% accuracy the absence of cancer.

The specification provides working examples that demonstrate that the methods disclosed in the specification are capable of screening for the presence of prostate cancer. The specification only needs to enable those skilled in the art to make and use the invention, not to provide a percent accuracy for the claimed screening method.

In response, first, the association of the absence of prostate cancer with the levels of inhibin is not the claimed invention, therefore, it is not an issue to be discussed here.

The Office agrees that claimed invention is drawn to a method of screening for a down-regulation of inhibin, which is indicative of having prostate cancer. However, as stated in the rejection, to satisfy the requirement of 112, 1st paragraph and obtain a patent, it is necessary that the specification provides an enabling disclosure of how to make and use the claimed invention. The objective of the claims is diagnosing present prostate cancer by a down expression of the inhibin levels. Thus, it would be expected that one of skill in the art would be able to diagnose the present (developed) prostate cancer without undue a quantity of experimentations by determining the levels of inhibin in the test individuals. The instant specification does not provide such enablement disclosure and the state of the art does not support claimed invention. As stated in the rejection, the specification provides small sampling (12 samples) showing poorly differentiated prostate cancer tissue compared to the adjacent non-malignant region of the prostate and the expression of the protein in basal cells of non-malignant regions of the malignant tumors. The state of the art indicates "the inhibin α-subunit was frequently over-expressed in high-grade prostate cancer" (Risbridger et al and "low or undetectable expression of α-subunit of inhibin in the primary prostate cancer" (Schailk

et al). Based on the limited samples, limited staining the malignant/non-malignant regions of the tissues provided in the specification, and inconclusive and contradictory results shown in the art, one skilled in the art could not practice the claimed invention drawn to a decreased levels of inhibin as an indicator for the presence of prostate cancer.

Applicant then argues the references by Gardes and Zhang et al., who teach inhibin-like peptide, which is different from inhibin. This has been carefully considered and is persuasive. However, based on the Mesh word search result, the human inhibin-like peptide has the inhibin activity and alternative name as alpha-inhibin 31 and heads to inhibin family (see attached). It would be appreciated if Applicant could provide further information such as sequence comparison indicating the structure and sequence differences between inhibin and inhibin like peptide.

Finally, the Office disagree with the conclusion made by Applicant on that the teachings of the cited references of co-inventor Risbridger et al., and Schaik et al., stating the results presented by both publications are completely consistent with the disclosure of this application in that the down-regulation of inhibin has been a persistent indicator for having prostate cancer as claimed. The reasons have been discussed above.

Thus, Applicant's argument has not been found persuasive, and the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/
Acting SPE of Art Unit 1643